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THE AlphaNetter

Advocacy Victory

By Miriam O'Day, Senior Director Public Policy — Alpha-1 Foundation

AlphaNet is pleased to announce that the treatment for Alpha-1 will be adequately reimbursed for Medicare beneficiaries in the hospital outpatient setting, ensuring patient access to care. On November 1, 2002 the Centers for Medicare and Medicaid Services (CMS) ruled that outpatient payments for Alpha-1 will be based on a "reasonable cost basis" removing the threat of deeply reduced reimbursement rates



The AlphaNet team in Washington, D.C.

that were proposed in August. CMS reported that their decision making was based on the unique nature of the product and the significant impact on beneficiaries that need access to care. The CMS regulation indicates that the Alpha-1 message regarding access to care was delivered and received. A hard fought battle has been won.

The Reserve Officers' Association overlooking the U.S. Capitol served as the prestigious headquarters for Advocacy Day. Attendees participated in a morning education and training program with guest speakers, Paul Billings, American Lung Association, Diane Dorman, National Organization for Rare Disorders (NORD), and The Honorable John S. Reid, State Delegate from Virginia. Fellow Alphas Fred Walsh and Cathy Valenti gave a presentation on Alpha-1 Medicare reimbursement and headed up a question and answer period improving knowledge of the issues for afternoon Congressional meetings.

Special awards were presented to members of Congress who have made contributions to improving the health care needs of individuals suffering with lung disease. Congressman Jim Ramstad (R-MN) was honored for his leadership in healthcare legislation and deep commitment to individuals with Alpha-1. Congressman Ramstad was the first to sponsor a letter stressing the urgent need for adequate Medicare reimbursement for plasma-based therapies. Congressman Joe Pitts (R-PA) quickly joined Mr. Ramstad as a co-sponsor of the letter that was sent to all Members of Congress for support. Following Advocacy Day the Ramstad/Pitts letter received 36 signatures from republican and democratic Members of the House of Representatives and was sent to Tom Scully, Administrator, Centers for Medicare and Medicaid Services (CMS). The signatures on the letter signify the commitment obtained by our advocates while visiting Capitol Hill and in subsequent communications with Congressional offices.

Comments from Advocacy Day attendees were overwhelmingly positive with many noting the empowerment they felt through addressing the issues they face with people who can positively impact health policy.

Advocacy Day was co-sponsored by the Alpha-1 Foundation and Alpha-1 Association. Bayer Corporation, AlphaNet and Aventis Behring provided generous corporate sponsorship.

What did we ask for on Capitol Hill?

Why did over 100 Alphas and their families travel to Washington, DC to highlight "Access to Care" in Congressional meetings? In April 2002 Medicare reduced benefits for the treatment of Alpha-1 and proposed additional cost containment for 2003. Advocacy Day provided an opportunity to request that members of Congress take action on behalf of the Alpha-1 Community as

— continued on page 4, column 1



## In Loving Memory of Lynda Lindsey

By Diana J. Patterson,  
AlphaNet Coordinator

"A tree is known by its fruit; a man by his deeds. A good deed is never lost; he who sows courtesy reaps friendship, and he who plants kindness gathers love."



Lynda Lindsey

Lynda always signed off on her email messages with these words. But more than that, Lynda lived by these words. I will always remember her with eyes shining, full of love and laughter, and caring so much for every one of us. And when I say caring, I mean truly caring. If she heard of a newly diagnosed Alpha, she would be the first one on the phone to call and offer compassion, and information, and assistance. She would make sure that, whoever it was and whatever their circumstances, they had all the help the Alpha community could offer. Even though she struggled every day with her own worsening condition, she never stopped giving and working for the Alpha-1 community.

I'll never forget the day I met Lynda. Traveling to my first national Alpha-1 conference in 1997, I walked into the hotel lobby alone and unsure of myself. Lynda was there. I don't know how she knew I was an Alpha, but she did. Within minutes she made me feel welcome, and part of the "family." Our relationship continued to grow over the years, after that initial meeting. She would call about someone she cared about, needing help. Or she would call about events taking place in the community, and looking for ways to volunteer her services. Or sometimes she would just call about me. I remember one time when she lovingly chastised me for "opening my windows" in the spring, afraid that I would get sick.

Her words of encouragement will live on, as will the memories of Lynda's impact on all our lives. And when she couldn't be with us in person, she was always there in spirit. Unable to attend the national conference this past June, she encouraged the rest of us with the following words: "Each of you go, with all the love I can send from Alabama, and enjoy every minute of each day you all spend together... please know that my heart and soul are there with all of you." And, when she couldn't be with us last spring, she said, "Smile, and I am smiling back at you all." May Lynda's smile be etched upon our hearts always.

## Nurses Corner

Janis G. Berend RN, MSN, C-ANP

I would like to spotlight a nurse from Colorado with whom I have worked for five years.

Karin Dunn, RN has worked with respiratory diseases for 35 years. She cares for many patients requiring home IV therapy, but her first love is administering Prolastin® for Alphas. For those Alphas who have received lung transplants, she follows them post transplantation. By administering infusions weekly, Karin gets connected with the person so she can answer questions, assist with doctor's plan of care and provide necessary teaching. By knowing Alpha-1, she recognizes problems as they occur, whether physical, psychological or social. Some of her experiences have included the following:

- Karin was able notice an Alpha was becoming cyanotic at times and evaluated the Alpha by oximetry noting her reduced oxygen levels, she contacted the doctor, and got the necessary supplemental oxygen. The Alpha hadn't noticed, and therefore did not address it with her physician.
- Noting increased amount and discolored sputum with shortness of breath, Karin initiated discussions about taking prescribed antibiotics and encouraged seeking medical attention early.
- Identifying medication side effects, drug interactions, drug allergies, ineffective medications, and whether they are eating and sleeping well, using & cleaning inhaler, spacer and nebulizer properly, initiated better communication with their doctor.
- Spending time with the Alphas helps Karin note any psychological issues and often allows the Alpha to "vent." One patient said they spend more time with her than busy family members. Karin also interacts with the family members and says, "You sometimes feel like family."
- Social issues may involve getting an Alpha connected with a support group. Karin has attended support group and educational meetings and often assists with organizing times, places and speakers.

Karin loves working with Alphas and states, "It's good to see new patients and assist them as they grow and adapt to this new and fearful diagnosis." Patients find comfort knowing she knows her job, does it well and goes the extra mile to provide special care.

## Alpha-1 Luncheon

By Kathy Haduck, AlphaNet Coordinator



L to R: D'Orazio, Haduck, Sandhaus

On August 24, 2002, twenty-two Alpha's met for the first time. The meeting was held in Monroeville, Pennsylvania. Those in attendance brought family members, nurses and even an insurance case manager, for a total of 40 guests.

Bayer Representative, Rob D'Orazio attended, as did Andrien Docken from Advanced Respiratory. Again thanks to both for spending the day with us, and especially for sponsoring the luncheon.

The highlight of the day was having Dr. Robert Sandhaus speak to the group. With very few exceptions, this was the group's first contact with an "Alpha Doc". As usual Dr. Sandy was great and made everyone feel comfortable and at ease. All were impressed with his knowledge of Alpha-1 and his willingness to take the time to answer their questions.

## Award Presentation

At their Annual Meeting on October 21, 2002 in Walpole MA, the American Lung Association of Greater Norfolk County recognized Fred C. Walsh as "Volunteer of the Year" for his outstanding efforts in the fight against lung disease and Bayer Pharmaceutical as "Company of the Year" for their support of Team Alpha-1 and the Alpha-1 community.

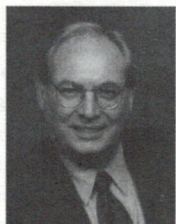


L to R: Fred Walsh, AlphaNet; Martha Waldron, American Lung Association; Joe Zuraw, Bayer Pharmaceutical

# Plasma Safety and West Nile Virus

By Robert A. Sandhaus, M.D, PhD., FCCP  
Medical Director and Executive VP,  
AlphaNet, Inc.

Infection with West Nile Virus (WNV) is a serious health risk to individuals with underlying medical conditions or advanced age. In normal individuals it usually causes mild illness or no symptoms at all. It is transmitted primarily by infected mosquitoes. Recently, West Nile virus has been transmitted by transplantation of organs from an infected donor. That donor may have contracted West Nile virus infection from blood transfusions. This raises safety concerns among individuals requiring treatment with plasma-derived therapeutics.



**Dr. Sandhaus**

## Background

The West Nile Virus is a flavivirus, a family of viruses which also includes the Japanese and St. Louis encephalitis viruses, Yellow Fever virus, and Hepatitis C virus. The West Nile virus is known to infect animals and humans and has a wide distribution throughout Africa, the Middle East, West Asia, and Eastern Europe. While the West Nile virus was first isolated in Uganda in 1937, the first reported cases in the Western Hemisphere occurred in New York in the summer of 1999. In humans, a majority of West Nile virus infections are "silent," causing no symptoms. In those with symptoms infected individuals often experience a mild flu-like illness including fever, rash, and gastrointestinal distress. In its most severe form, affecting less than 1% of infected individuals, meningitis and/or encephalitis can occur with muscle weakness, confusion, urinary retention, and respiratory distress. The most severe cases have been fatal. Infections of horses and birds are of great veterinary concern as well.

West Nile Virus has advanced rapidly in the US during the summer of 2002 to include much of the Eastern two-thirds of the US. Confirmed cases in animals, humans, mosquitoes, or birds have been reported in all states except the seven westernmost. Even so, by the end of August 2002 a total of only 673 people in 27 states have been sickened by this infection in the US and a total of 32 people have died.

There is no simple or rapid test to identify the West Nile virus in affected individuals. Most diagnoses are made by sending tissue samples to central laboratories. This makes rapid identification or screening of donated blood impossible at the present time.

## Reducing the Risk of Exposure

The best way to avoid the West Nile virus is to avoid exposure to mosquitoes. If you live in a state with known infections, some ways to accomplish this are:

- Reduce time outdoors, especially in the early evening hours.
- Wear long pants and long sleeved shirts.
- Apply mosquito repellent containing DEET (N, N-diethyl-m-toluamide) to exposed skin areas following the manufacturer's recommendations for dosing frequency, application, and clean-up.

Public health authorities have also undertaken measures to destroy mosquito habitats and to spray insecticides that kill mosquitoes. There is active research in the area of vaccine development.

## Risk to Plasma Products

Currently there appears to be little to no risk of transmission of West Nile virus infection via plasma products. There are several reasons for this:

- All plasma-derived therapeutic products undergo viral reduction and/or viral inactivation steps to reduce the risk of transmission of viral infections. These steps have been shown to protect against the type of virus that causes West Nile virus infections.
- Most plasma donations are quarantined for many months prior to release and therefore current plasma products are manufactured from plasma collected prior to the current West Nile virus outbreak.

There is additional work that needs to be done as quickly as possible to ensure the safety of plasma products. An assessment needs to be made regarding any specific questions that should be included during donor questioning that would be specific for West Nile virus infection. Great importance is the development of testing for West Nile virus infection in blood and plasma. Such testing will need to be rapid, accurate, and able to be widely disseminated.

## Summary

It does not appear that the West Nile virus presents a safety issue for patients

receiving plasma products at this time. Accurate and widely available testing methods to identify West Nile virus in blood and plasma need to be brought forward quickly. Further work is needed to evaluate screening questions for plasma donors and to confirm the effectiveness of viral inactivation and reduction techniques during the processing of plasma-derived therapeutics. These efforts need to be expedited to ensure the safety of our plasma products.

## Netter Notes

By Diane Eaton

Dugan Reed an Alpha 1 patient rode the Great Ohio Bicycle Adventure (350 miles) with his sister in law, Diane Eaton. Dugan is 44 years old and currently has 28% lung function. He trained for a year to finish this ride, losing 70 pounds in the process.



**Dugan Reed**

Since Dugan is on oxygen and can only carry one tank at a time, Diane pulled a trailer with 5 bottles of oxygen. Dugan's ride is a testimony of what a person can accomplish when you have a goal to achieve. He was particularly happy with the fact that he did not walk any hills, and even rode past people walking the hills. He said he could even win this race, if we did not have to stop and change tanks or answer the cell phone!

## Congratulations

Congratulations to Gayle Allison for being awarded AlphaNet's 2nd Annual Nancy C. Ferguson Award for excellence in service to the AlphaNet Community, and to Darrell Nall for being awarded the Exceptional Service Award in recognition for his extraordinary efforts to further AlphaNet's mission. The awards were presented at the AlphaNet Coordinators training meeting in Coral Gables, Florida on September 27, 2002.

– continued, Alpha-1 Advocacy

CMS reclassifies the sole therapy for the treatment of Alpha-1.

#### **Medicare Reimbursement:**

- Advocates requested Congressional support for the Ramstad/Pitts letter to CMS Administrator Scully.
- Advocates requested Senate support for a "Dear Colleague Letter". Following Advocacy Day many members of the Senate wrote to Administrator Scully. Through the urging of AlphaNet and the Pennsylvania Alphas, Senator Santorum (R-PA) initiated a letter and asked all members of the Senate to join him. Many Senators signed on in support.
- Advocates asked for an Alpha-1 specific cost study that would provide government sponsored data and protect Alpha-1 treatment from extreme cost reductions. Because Alpha-1 is a rare disorder, CMS review of hospital claims data does not represent the true cost of treatment for Alpha-1. The cost study was also designed to explore a home health care benefit for Medicare beneficiaries.

#### **Rare Disease Funding:**

- Advocates requested support for HR 4014, which doubles the budget for the FDA, Office of Orphan Product Development (OOPD) over the next four years. The OOPD will use the majority of this increase to fund clinical research grants. New treatments for Alpha-1, including gene therapy, may result from the doubling of the OOPD budget.

- Advocates requested support for HR 4013, which doubles the NIH, Office of Rare Diseases (ORD) funding over the next four years. The ORD was established in the early 1990s to meet the neglected needs of 25 million Americans suffering with 6,000 rare "orphan" diseases in order to stimulate and coordinate research in rare diseases.

#### **Reimbursement Update**

The Alpha-1 Foundation's primary concern is to ensure "access to care", particularly for Medicare beneficiaries. To achieve access adequate reimbursement is essential. The Foundation has pursued a multi-pronged approach to resolving proposed cuts in Medicare benefits in the hospital outpatient setting which include: addressing administrative rule making, garnering Congressional support, working with numerous coalitions and seeking legislative relief.

The Foundation joined a Task Force formed by the National Organization for Rare Disorders (NORD). The Task Force goal is to obtain an amendment to the Social Security Act that will provide individuals receiving orphan therapies, including the treatment for Alpha-1, with reimbursement that is adequate to sustain patient access.

The Task Force amendment requires Medicare to model outpatient reimbursement on other sites of service, such as a physician's office setting. This would be preferable to using other methods of data analysis which do not reflect the cost of administering therapies for rare disor-

ders. The Task Force worked diligently to have the amendment added to the Senate Medicare reform bill and found that our provision had been cut out in the final draft. However, it now seems unlikely that Congress will pass a Medicare Reform bill prior to recessing. Numerous meetings held with Task Force representatives and Members of Congress resulted in strong support for the amendment. Several Congressional Members have vowed that they will address rare disease therapies with CMS Administrator Scully, requesting that CMS revise the reimbursement rate prior to issuing the final rule on the Hospital Outpatient Prospective Payment System.

## **Announcement**

In their ongoing effort to keep the alpha-1 community up-to-date on Prolastin® shipments, Bayer Direct announced a new service offered through its toll-free number: 1-800-305-7881 (Option #1). This new service is available 24 hours a day and provides regular updates on Prolastin® shipments. The service features a recorded announcement that is updated weekly, or as new information becomes available.

**NOTE:** Please notify your AlphaNet Coordinator of any changes in your health status, insurance coverage, nursing services, and/or pharmacy concerns.

### **The AlphaNetter**

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*Return Service Requested*

