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THE

AlphaNetter

Dear AlphaNet Member

On behalf of our Board of Directors, I would like to recognize and thank you for your role in supporting the Alpha One Foundation.

During the nine months ended March 31, 1999, AlphaNet contributed a total of \$125,000 to the Alpha One Foundation. This amount is in addition to the \$200,000 donated to the Foundation by AlphaNet during the last two fiscal years.

As you probably know, both the Foundation and AlphaNet are not-for-profit charitable organizations and all excess revenues generated by AlphaNet are given to the Foundation to support research efforts and other programs of the Alpha community. Because of your membership in AlphaNet, the Alpha One Foundation has been able to fund Phase I of an alpha₁-antitrypsin deficiency "Cost of Illness Impact Study," to provide start-up funds for the development of the Alpha One Research Registry and to help build the infrastructure to enable ongoing research activities.

The Foundation truly appreciates your participation in the AlphaNet program, the dedication of the AlphaNet coordinators, and the vision of the founders, Sandy Lindsey, Susan Stanley and John Walsh. Together, you embody AlphaNet's purpose, "Alphas Serving Alphas."

Sincerely,

Karen L. Fraser
Chair, Board of Directors
Alpha One Foundation



Karen L. Fraser

Dear AlphaNetter

Thank you for your continuing commitment to AlphaNet. As a consumer of AlphaNet services you know best what we do and how we need to do it. It is in this light that we write to you for your suggestions for nominations to the Board of Directors of AlphaNet, Inc.

Current members of the Board of Directors for AlphaNet, Inc. include:

- Alexandra J. Lindsay
Miami, Florida
- Robert A. Sandhaus, M.D., Ph.D.
Denver, Colorado
- William E. Stark
Palatine, Illinois
- John W. Walsh, *Chairman*
Miami, Florida
- Susan Stanley, *Director Emeritus*
Traverse City, Michigan

A profile of the current Board and information regarding the desired profile, talents and areas of expertise for board members follows. We welcome your thoughts and comments as well as recommendations.

Current Board Profile includes 2 Alphas, 1 Physician, 1 Business Executive
Gender: 3 male, 1 female
Nationality: 4 Anglo-Saxon
Geography: Florida, Illinois, Colorado
Current Areas of Expertise: *business management, marketing, pharmaceuticals, not-for-profit organizations*

Available Seats: 3

Term: *To be determined*

A general profile for nominees should include both male and female, represent geographic diversity, and express no preference for race or ethnicity.

Recommendations for representation on the AlphaNet, Inc. Board of Directors:

Alphas: *Either ZZ or MZ, with full working knowledge of alpha₁-antitrypsin deficiency*

— continued on page 4, col. 1

Prolastin Shortage

Statement to Health Care Providers Regarding Augmentation Therapy during Reduced Allocation and Availability of Prolastin

Dear Colleague:

This letter is to inform you that based on Bayer's notice of March 31, 1999 (shown at right), effective April 1, 1999, Bayer has decreased the allocation of Prolastin® (alpha 1 proteinase inhibitor) from 100% to 60% to all customers. It is anticipated that this reduced allocation will last 3 months or more. This reduced allocation is over and above the shortages that existed for the past fifteen months. Even at 100% of allocation, supply has not been sufficient to meet current demands and the increased demands of newly diagnosed patients. Until new products become available, this shortfall is expected to continue.

The most rational as well as scientifically defensible patient-physician response to the Prolastin shortage was addressed last year in a joint statement of the Alpha 1 National Association and the Alpha One Foundation. It was pointed out in this statement that there is no data to indicate that taking less than the recommended FDA approved dosage of Prolastin (60mg/kg/week) is of any benefit. Indeed, recent dosing studies with alpha1-antitrypsin indicate that 30 mg/kg doses do not significantly increase lung levels of above baseline [1]. Furthermore it was emphasized that Prolastin therapy is only one component of the treatment of the lung disease associated with alpha1-antitrypsin deficiency. Prolastin is a therapy designed to influence the long-term course of the disease. Short periods of time off Prolastin should not be considered harmful. (In the USA 1998 NHLBI sponsored Registry study, no significant difference was noted between those who were intermittently treated versus those always on augmentation therapy 2). Overall therapy includes bronchodilators, early use of antibiotics, pulmonary rehabilitation, lifestyle changes, particularly smoking cessation, and flu and pneumonia vaccines 3). Within this context, Prolastin plays an important but additive role.

A statement from the European Respiratory Society (ERS) in response to their more dramatic reduction of Prolastin allocations, recommended use of Prolastin during acute exacerbations or pneumonia. The rationale for this approach is based on the following evidence: 1) alpha1-antitrypsin is an acute-phase reactant that is known to increase its concentration by 1.5-3.0 fold in response to pneumonia. This observation likely indicates biological "need" for increased alpha1-antitrypsin during periods of infection or inflammation, 2) acute exacerbations or respiratory infections are associated with an influx of neutrophils and hence the destructive lung protease neutrophil elastase 4, 7-12], 3) the largest losses of lung function likely occur following acute infections 13].

In counseling your patient on dosing strategies during this acute shortage, it is appropriate to consider three or more weeks supply of Prolastin (i.e., the FDA-approved dose of 60 mg/kg/wk) be kept in reserve to use at the time of acute exacerbations or infections. For patients who are acutely ill with a respiratory infection, every effort should be made to obtain full weekly doses of 60 mg/kg/wk.

If you have any questions regarding this approach to the management of your alpha1-antitrypsin deficient patient please do not hesitate to contact the Alpha One Foundation (888-825-7421) or the Alpha 1 National Association (800-521-3025). These organizations will be happy to provide you with the citations relevant to management of your patient during this shortage. They can also provide referral to a physician on the Medical and Scientific Advisory Committee of the Alpha One Foundation, or to one of the Foundation's regional Clinical Resource Centers, who will discuss specific issues of management.

Sincerely,

Mark L. Brantly, M.D., Robert J. Fallat, M.D., Michael Krowka, M.D., Robert A. Sandhaus, M.D., Gordon L. Snider, M.D., James Stocks, M.D., and Gerard M. Turino, M.D.

Bayer 

Pharmaceutical
Division

Bayer Corporation
400 Morgan Lane
West Haven, CT 06516-4175

March 31, 1999

Dear Bayer Customer:

Effective April 1, 1999, we will be decreasing your allocation of Prolastin® (alpha 1 proteinase inhibitor (human)) from 100% to 60% of your average monthly purchases during the period of October-December 1997. This allocation system was originally initiated in January 1998 in order to distribute available product in the most equitable fashion.

The slowdown in Prolastin® releases is the result of a number of issues. Key to this is the execution of more detailed validation plans for our production equipment and processes. We have also extended our scheduled maintenance shutdown in our Clayton, NC facility. The extended shutdown was necessary to optimize the incorporation of upgrades and improvements to our facility and equipment, some of which can only be accomplished when areas of the plant are not operating. These improvements will ensure continued compliance with current good manufacturing practices (cGMP) and will minimize downtime over the long term. The extended shutdown will affect releases two to three months from today.

Accordingly, Bayer is taking corrective action now to control releases and ensure a more orderly distribution of product in the coming months. These circumstances will lead to lower product releases for the next few months. We will continue to monitor our supplies and adjust the allocation accordingly. As you know, unforeseen problems can also affect the scheduled releases of our products.

It is important to note that the current allocation program is in no way intended to guide dosing considerations for patients. Patients with questions regarding dosage or any other treatment concerns should consult with their physicians.

We at Bayer recognize our responsibility to the patients who depend on Prolastin®. We continue to release product from both our Clayton, NC and Berkeley, CA facilities. Additionally, we are expediting packaging and distribution of Prolastin® lots currently in process and are working closely with the FDA to speed product releases.

A Bayer Clinical Communications Specialist is available to answer clinical questions regarding Prolastin® by calling 1-800-288-8371.

If you have any questions concerning your allocation, please contact our Customer Service Department at 1-800-243-4153.

Thank you for your understanding and cooperation during this difficult period.

Sincerely,

Maura S. Fashjian
Assistant Product Manager

Joseph Zuraw
Product Manager

REFERENCES

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2. Survival and FEV1 Decline in Individuals with Severe Deficiency of alpha1-Antitrypsin. Am J Respir Crit Care Med, 1998. 158(1): p. 49-59.
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10. Knight, K.R., et al., The proteinase-antiproteinase theory of emphysema: a speculative analysis of recent advances into the pathogenesis of emphysema. Respirology, 1997. 2(2): p. 91-5.
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PROFILE: Alpha Nancy

Nancy Ferguson was diagnosed with Alpha1 eight years ago, and it changed her life, and not just in bad ways. Despite her low lung function, once she found a group of other Alphas, she threw herself wholeheartedly into the effort to educate and help others. It gave her a purpose in life that wasn't there before. Nancy immediately became an important part of her local support group, the state organization and the National Association. She served a two-year term on the National Board of Directors and was the Coordinator for the National meeting held in San Francisco in 1994. After that meeting, Nancy also wrote the manual that is still used to plan National and Regional meetings.

Writing is one of Nancy's strong suits — she wrote and edited a California newsletter for three years, *As I Live & Breathe*, and has been writing a local newsletter for her support group for many years. Nancy has been a speaker at National and Regional meetings and didn't miss a one until illness prevented her from attending the Portland conference last year. This was especially disappointing,

because she had done so much work to organize the hotel and enlist speakers.

Organizational skill has been one of Nancy's main work assets as well. She was employed by a national home health company before coming to AlphaNet in April 1997. Her experience with a home health pharmacy made her the logical choice to be the Pharmacy Liaison for AlphaNet. She made trips to Cleveland and helped the pharmacy to understand the needs of the Alpha1 consumer. Nancy worked the conferences and talked with the AlphaNet members, continually educating anyone who would listen about Alpha1. During last year's Prolastin shortage, Nancy did the breakdowns each month to be sure everyone got their fair share of the precious few milligrams we were able to purchase. As her physical life changed because of Alpha1, she brought that information to her colleagues and members, talking about new medications, living alone with a chronic illness, pulmonary rehab, and the transplant evaluation process.

Nancy was listed for a double lung transplant at Stanford Medical Center in November 1998. Through worsening health, she knew it was a matter of time before stopping work and going on disability would become necessary. That



time arrived this January with a hospitalization for pneumonia and two cracked ribs. Although she has recovered, Nancy's new job is taking the very best care of herself that she possibly can. And we're sure she'll be talking and writing about it!

We'll miss you, Nancy, and can't wait to see you again with two healthy lungs.

Nancy Ferguson served as an AlphaNet Coordinator for the Western US from 1997-99.

Editor's Corner

Thanks for your remarks concerning our first issue of The AlphaNetter. Comments were overwhelmingly positive. The January issue, however, did include a few news items that were incorrect or could have been misinterpreted. So, to set the record straight...

Corrections — Netter Notes

- The Walsh Family presented the Helen Chase Walsh Award to Viki Reed.
- The 1998 Alpha1 Christmas Cards were funded entirely by the Florida Chapter of A1NA.

Clarification — AlphaNet Milestones

During the fiscal year ended June 30, 1998, AlphaNet contributed a total of \$8,093 toward sponsorships of Alpha1 Regional and National Educational Conferences, provided a \$6,500 research grant to the University of Delaware for Christine A. Cannon's study of marital stress and coping with alpha₁-antitrypsin deficiency, paid \$3,094 for the Florida Chapter's 1997 Alpha1 Christmas Cards, and made an educational grant to the A1NA of \$4,000 toward the publication of (continued page 4, col. 3)

Using Websites As a Health Resource

— by Joyce Finch

With the arrival of Spring come the allergic reactions to the buds on the trees, and all the airborne pollens. There are several websites that you can go to for maps of your area regarding pollen information:

- ◆ <http://www.aaaai.org>
(the American Academy of Allergy, Asthma and Immunology) Just click on "Pollen/Spore counts."
- ◆ <http://www.weather.com>
(the Weather website) Click on "Health and Allergy" which will take you to an allergy site for "respiratory distress" which will show you a map of the United States. If you think that a weather-related low coming through your area will affect your breathing, the "respiratory distress" map will show you if in fact there is that problem in your state.
- ◆ <http://americanheart.org>
(the American Heart Association website) Questions about your heart? Of course you will still need to check with your doctor if you have any questions or concerns.

For access to medicines and vitamins via the Internet, you might want to log on to one or both of the following websites.

- ◆ <http://drugstore.com>
A new website to look into, especially if getting out of the home is a problem for you.
- ◆ <http://altmed.od.nih.gov>
(for alternative medicines)
- ◆ <http://vitaminshoppe.com>
(for vitamins)

You can do a search for any information that you want to find with your computer, using the Internet. Have fun!

*Joyce is the Midwest States Regional Coordinator for AlphaNet. She resides in Michigan with her husband, Ed; her three adult children reside in the same town. She can be reached at:
Phone: 888.225.9012 - x 210
E-mail (work): Joyce@Alphanet.org
E-mail (home): jfinch@iserv.net*

— continued, BOARD NOMINATIONS

Professional Expertise: *Accounting, Law, Medicine*

Business Expertise: *Health Care Industry, Pharmaceuticals, Pharmacology, Insurance, Marketing, Computer Technology*

Please send your recommendations to Sandy Lindsey, c/o AlphaNet, 2735 SW 27th Avenue, Miami FL 33133 or e-mail to: ajlindsey@worldnet.att.net. Include your reasons for recommendation and phone number of the person(s) you suggest. The nominating committee will review the suggestions and potential nominees will be asked to submit a resume and will be interviewed. Following due consideration, a slate will be presented to the Board for election at the next meeting of the Board of Directors.

AlphaNet will be better for your input.

Sincerely,

Sandy Lindsey

Sandy Sandhaus, M.D.

The Registry

Be Part of the Solution. For those of you who have not already joined the Alpha One Research Registry, an enrollment questionnaire is available by calling 888-825-7421 – ext 215.

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

Netter Notes



Linda Maxwell, Nancy Corbin, Mary Pierce and Paulette Story at Sonny's Barbeque

- ◆ On January 19, the Suncoast Alpha's Support Group, facilitated by Marta Strock and Doris Stark, enjoyed a feast at Sonny's Barbeque in Sarasota, FL. Our Team Alpha Captain, Mary Pierce, was the guest of honor. Mike Levine, owner of Sonny's, along with AlphaNet, picked up the tab. Fun was had by all!
- ◆ AlphaNetter, Shirley St.Cyr, will ride in the American Lung Association of New Hampshire's 1999 Seacoast Bike Tour scheduled for May 22-23. Team Alpha's participation in this 2-day event is sponsored by Bayer Corporation. Anyone wishing to participate should call Shirley at 1-888-825-7421 ext. 213.



Shirley St.Cyr will be riding "Bayer-backed" during the NH Seacoast Bike Tour.

- ◆ The American Lung Association of Greater Norfolk County is sponsoring the Massachusetts Alpha 1 Support Group meeting for April. The main speaker will address "Breathing techniques" for Alphas.

- ◆ Any AlphaNetter planning to attend the Alpha 1 National Conference, May 15-17, please contact your coordinator.

In Memorium. Our thoughts and prayers go out to the families of AlphaNetters who passed away since January 1.

- ◆ Dan Akers (the husband of AlphaNetter, JoAnn Denton)

- ◆ Robert Lee

— continued, EDITOR'S CORNER

Understanding Pulmonary Function Tests. Additionally, in July 1998, AlphaNet contributed \$2,500 to the A1NA for sponsorship of its Hot Shots Golf Tournament.

Our use of the word "funded" in the "Milestones" column was not intended to imply that AlphaNet had paid for these programs and projects in their entirety. We recognize that the program costs substantially exceed our contribution levels and that other companies, A1NA members and individuals support the A1NA with significant contributions. The purpose of the article was to give feedback to the AlphaNet members about how a portion of the insurance payments that are made on their behalf is ultimately returned to the Alpha community. AlphaNet members should take great pride in their contribution, indirect as those contributions may be.

To those who have interpreted our meaning otherwise, we apologize. To AlphaNet members, thanks again.

The AlphaNetter

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