

Spring 2005

The National Alliance for Thrombosis and Thrombophilia

NATT

www.nattinfo.org

KNOWLEDGE IS POWER!

*Did you ever think: Is this really true?
When you are dealing with BLOOD
CLOTS, knowledge can save your life.
Now that's power!!*

*Welcome to the first edition of the
newsletter of the National Alliance
for Thrombosis and Thrombophilia
(NATT). Through the newsletter and
its sister website, www.nattinfo.org,
we hope to regularly provide you
with news and information to help
you increase your knowledge about
thrombosis and thrombophilia. Whether
you are suffering from thrombosis or
thrombophilia, know someone who is,
or are just seeking to learn more about
these disorders, please know that you have
a unique opportunity to help NATT
make a difference in reducing the tragic
losses (60,000 dead) and debilitations
(200,000 new patients) resulting from
thrombosis and thrombophilia each year.*

*Staying informed through the newsletter
and the website is an important first
step. Let us know what you need and
let us know how you can help. We hope
that you will join us in our quest to
brighten today and ensure tomorrow
for those suffering from thrombosis and
thrombophilia.*

*Best regards,
Mark E. Jablonski*

PRESIDENT
NATIONAL ALLIANCE FOR THROMBOSIS
AND THROMBOPHILIA

It is with great joy that we write to tell you how much NATT has grown in the last 21 months. As you may know, NATT is a nationwide, community-based, volunteer health organization that was created in August 2003, with our histories of blood clots as our motivation. Our charter members attended a thrombosis and thrombophilia awareness meeting at the Centers for Disease Control and Prevention. From this meeting, NATT was established. Our goal is to ensure that people suffering from thrombosis and/or thrombophilia receive early diagnosis, optimal treatment and quality support.

Our long term objectives are to:

- create a grassroots advocacy network
- pursue national policy agenda
- develop standards of care
- increase the availability of high quality care
- encourage, enable, and initiate research
- promote educational activities
- develop patient support groups throughout the country

Through research, education, support and advocacy, we have accomplished many goals in our first year. We:

- were incorporated in December 2003
- received our 501-C-3 status in December 2004
- launched our website www.nattinfo.org
- recruited prestigious Medical and Scientific Advisory Board members
- met with the Centers for Disease Control and Prevention and developed a formative research project to determine the specific needs of patients who have suffered from or are at risk of thrombosis
- were featured in Redbook magazine for an article on thrombosis
- sent a letter to all Congressmen and Senators introducing NATT
- participated in a workshop organized by the American Society of Hematology for NATT in May 2004.
- identified existing education material for patients and materials that need to be prepared
- had three patient education seminars in 2004: Denver, Charlotte, Detroit
- had a patient education seminar in April 2005: Chicago

Our 2005 priorities are to:

- develop additional patient education seminars
- produce a regular newsletter
- create educational materials
- continue advocacy efforts
- secure regular funding for the organization
- start work on defining standards of care for thrombosis and identify research priorities

It is your voice that makes a difference. We truly appreciate your support.

Lori Preston, MBA
Vice President
Chair-Communications Committee





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First meeting of the Medical and Scientific Advisory Board, December 2004. Left to right: Dr. Bruce Evatt, MASAB, Dr. Stephan Moll, Chair, MASAB, Sally Crudder, Centers for Disease Control and Prevention, Dr. Edward Libby, MASAB, Line Robillard, NATT executive director, Mark Jablonski, NATT president. Missing: Marilyn Manco-Johnson, MASAB.

What is DVT?

Deep vein thrombosis (DVT) is a condition resulting from the formation of a blood clot inside a deep vein, commonly the calf or thigh. DVT occurs when the blood clot either partially or completely blocks the flow of blood in the vein.

Who is at Risk For DVT?

Anyone could potentially develop a DVT. The likelihood of developing DVT increases with age, and DVT occurs most commonly over the age of 60. However, there are certain risk factors that increase the chance that any person will develop a DVT. These include:

- Smoking
- Obesity- Body Mass Index over 30
- Immobility
- Hospitalization
- Surgery or trauma
- Pregnancy
- Hormone based contraceptives
- Some chronic medical conditions (such as diabetes, inflammatory bowel disease or congestive heart failure)
- Air travel (long-distance)
- Hereditary thrombophilias (such as deficiencies of protein C, protein S, or antithrombin; factor V Leiden, prothrombin gene mutation)
- Some acquired blood conditions (such as antiphospholipid antibodies or elevated levels of homocysteine)

Practical Steps to Minimize Risk

- Try to maintain ideal body weight for your height and gender.
- Stay active and try to get regular exercise.
- Avoid prolonged periods of immobility. For example, on a long car trip, stop and walk around every few hours. On an airplane, drink plenty of water to avoid dehydration, walk the aisles, do calf raises and toe squeezes and avoid alcohol. Wearing elastic stockings with a moderate level of compression (15 to 20 mm Hg) may prevent DVT from developing on long flights.
- Don't smoke.
- If you have other chronic medical conditions, such as diabetes, high cholesterol, or congestive heart failure, work with your doctors to try to keep these problems under good control.
- Talk to your doctors about the risk of thrombosis and the use of blood thinners or compression stockings for prevention of blood clots if you are pregnant, use birth control pills, are hospitalized or have surgery. This is especially important if you have a hereditary thrombophilia.

Reference: Ornstein DL, Cushman M. 2003 Factor V Leiden. Circulation. 107:e94-e97

NATT joins *The Coalition to Prevent Deep-Vein Thrombosis*, helps prepare for DVT Awareness Month 2005

Cynthia Kos, NATT Volunteer

NATT has expanded its network of influence by joining The Coalition to Prevent Deep-Venous Thrombosis, an alliance of healthcare professionals, policy-makers, and public health leaders determined to make DVT and PE awareness a national healthcare priority.

Representatives from the 37 organizations that comprise the Coalition met on January 28, 2005 in Washington, DC for the annual meeting. NATT board members Lori Preston and Randy Fenniger were in attendance, as well as Cindy Kos, who serves both the Education and Communications committees. The meeting centered on preparations for the upcoming DVT Awareness Month in March, and to introduce the new national spokesperson for DVT awareness, Melanie Bloom, widow of the NBC-news reporter David Bloom, who died of a massive PE while reporting in Iraq.

The Coalition formed when national healthcare organizations such as the American College of Chest Physicians and the Society for Hospital Medicine (SHM) discussed public, provider, and legislative apathy towards DVT at a Public Health Leadership Conference sponsored by the Centers for Disease Control and the American Public Health Association in August 2003. The first official Coalition meeting was held January 21, 2004 in Washington D.C. at the National Press Club, with the main objective to generate excitement and solicit involvement. The meeting resulted in the inaugural DVT Awareness Month in March 2004 and various media spotlights. The total number of print impressions generated by the first ever DVT Awareness Month grew to over 120 million.

This year's Coalition meeting featured high-profile physicians and caregivers, including U.S. Deputy Surgeon General Rear Admiral Kenneth P. Moritsugu, M.D., M.P.H., Dr. Laurence D. Wellikson (CEO, Society of Hospital Medicine), Dr. Kenneth Kizer (President and CEO, National Quality

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Forum), Dr. Geno Merli (Office of Surgeon General and Director of Internal Medicine, Thomas Jefferson Medical College), and Dr. Franklin Michota (Associate Professor of Medicine, The Cleveland Clinic Foundation).

The Coalition focused on its plans to target patients, physicians, and legislation by urging members to promote DVT

Awareness Month via their organizations' websites, local press releases, and newsletters. In addition, there was a brief speech which unveiled this year's public service announcement by Melanie Bloom. Mrs. Bloom received over 80,000 letters after learning that her husband, David, died from a PE while reporting for NBC News in Iraq. Not knowing at the time, Mr. Bloom's clot risk was high from immobility, dehydration, and by carrying the silent risk factor, Factor V Leiden. The immense national support and attention inspired Melanie to serve as a spokesperson on behalf of the Coalition to Prevent Deep-Venous Thrombosis. This spring, she will be speaking to various health groups, state legislatures, and is scheduled to appear on nationally-televised morning talk shows.

NATT will continue its involvement in the upcoming year and looks to utilize the resource materials provided by the Coalition to further our own mission of education and awareness. To learn more about obtaining these materials and The Coalition To Prevent Deep-Venous Thrombosis, visit www.preventdvt.org.



Left to right: NATT volunteer Cindy Kos, Melanie Bloom, Coalition spokesperson, Lori Preston, NATT vice president.

Advocacy efforts play important role in improving awareness, health care.



Randy Fenninger, Chief Lobbyist for NATT

Among the important missions of NATT are to increase awareness of thrombosis and thrombophilia, improve the quality of medical care available to individuals who experience these conditions and to promote fundamental scientific research into these areas. This requires interaction at a number of levels, including academia, hospitals, corporations and the federal government.

As a Washington lobbyist and PE survivor who serves on the NATT board, I want to outline the opportunities available to NATT in the nation's capital and discuss steps taken to date to make the most of those opportunities.

The missions of three federal agencies directly impact NATT's goals. All are part of the Department of Health and Human Services and are the National Institutes of Health (NIH, biomedical research), the Centers for Disease Control and Prevention (CDC, prevention and control of disease), and the Agency for Healthcare Research and Quality (AHRQ, standards of medical care).

CDC Relationship

The relationship with CDC is well established. In fact one might compare CDC to the labor nurse present at the birth of NATT. The agency is already funding efforts to collect data on thrombosis and thrombophilia through grants to eight hemophilia treatment centers. As this information is collected, CDC and NATT can analyze it to determine the best ways to reach out to individuals at risk to ensure they access the healthcare system on a timely basis, to build physician awareness of thrombosis and thrombophilia and to educate the public on ways to prevent thrombosis. NATT's Medical and Scientific Advisory Board also works closely with CDC. In addition to maintaining regular contact with CDC personnel, NATT is also working with Congress to increase the funding for these important activities.

The House and Senate Appropriations Committees allocate the funds for CDC each year, in particular by the Subcommittees on Labor, Health and Human Services and Education. Much of the agency's

money is "earmarked", that is, specifically directed by Congress to be used for a certain purpose. These earmarks are usually found in the Committee's report language, which provides direction to the agency on a number of topics. Last year NATT made an initial foray into getting some directive report language and a similar effort is underway now. The goal is to have Congress allocate additional money to CDC for its education and outreach efforts in thrombosis and thrombophilia.

National Heart, Lung, and Blood Institute (NHLBI)

Despite the widespread incidence of blood clots, it is surprising how much is not known about them. There is room for a much more intensive research effort into the entire field. This is where the National Institutes of Health comes into play and the lead at NIH falls to the National Heart, Lung, and Blood Institute (NHLBI). Within NHLBI, the blood diseases program controls most of the federally funded research in thrombosis.

The Medical and Scientific Advisory Board has developed a list of research priorities and in February, the Chairman, Stephan Moll, MD, NATT VP Lori Preston and I met with senior staff of the blood diseases program to discuss research needs and opportunities.

This is another area in which Congress can play a role through the appropriations process. Using the committee report and directive language, Congress can encourage NIH to accelerate its programs in certain areas. As we refine our research agenda, NATT will pursue this route as well. However, greater consensus among clinicians and scientists needs to be achieved before the Congressional route can be very productive.

During the meeting with the blood diseases division, we learned about NHLBI's Of-



Introducing NATT during meeting of CDC's thrombosis pilot sites. Left to right: Dr. Bruce Evatt, MASAB, Line Robillard, NATT executive director, Sally Crudder, Centers for Disease Control and Prevention, Sara Critchley, Centers for Disease Control and Prevention, Pat Koppa, NATT Board of Directors, Elizabeth Varga, NATT Board of Directors and MASAB.

Office of Prevention, Education and Control, which conducts a variety of educational programs directed at consumers and health providers. We will be meeting with their staff since this appears to be a very good place for a consumer oriented organization like NATT to interact.

NATT is joining other consumer and professional societies in NHLBI's affinity program, which brings together a variety of stakeholders on a regular basis to learn more about the Institute's activities. Not only can NATT learn more about an important agency's work, but participation also raises the visibility of the nation's only consumer organization devoted to thrombosis and thrombophilia.

Standard of Care

A most important goal of NATT is to raise the standard of care for people who experience blood clots. Too many of us have been misdiagnosed or provided inappropriate treatment. Much work needs to be done to raise the bar on the standard of medical care. Not long after I joined the NATT Board, I inquired about the standard of care for an individual with DVT or PE. I was told that none exists. As consumers, we should not accept this state of affairs. While it is important that every blood clot be properly diagnosed and treated, it is critical that individuals at high risk of clotting understand what good medical care should be and also receive it when necessary. This requires an educated consumer and educated medical personnel.

The Agency for Healthcare Research and Quality is the federal agency most oriented to these concerns. Much of its work is geared to helping physicians set evidence-based standards for treatment, improving medical outcomes and promoting the development of guidelines for medical care in a variety of areas.

All of these activities require the support of NATT volunteers. Just as we realize the important role of Congress and federal agencies, so do many other worthy organizations. We will need to work hard to make sure that the NATT message gets on the radar screen of every Member of Congress and every agency official. There is a lot of competition for Members' time and attention, which we will need to overcome.



Lynn Levitt's Story

When I awakened from a deep sleep on the morning of June 12, 2003, I had no idea what the awful pain in my right side was. Could it be the hotel bed that I was sleeping in, the heavy box I had moved earlier in the day, a cold coming on?

I continued to try and "self-diagnose" for the next week and a half until one evening my husband Rob and I were out for a walk. I began complaining of shortness of breath, and when we got home, I noticed that my right leg was severely swollen. With these two symptoms and with the persistent pain in my side, we decided I needed to be seen by a doctor.

Rob took me to the Emergency Room where I filled out the necessary form at the front desk describing my symptoms. I hadn't made it to the waiting area when the nurse rushed me to the evaluation room. Before I knew it there was a commotion around me...me!?! I couldn't have dreamed that there was really something so wrong with me. The ER doctors began to run tests and upon seeing the results of the chest CT scan concluded that I had a pulmonary embolism and multiple deep vein thromboses in my right leg. We didn't have a clue what any of this meant and I asked if I could get dressed and go to work.

I was admitted and moved into a room within 2 hours of first checking in at the ER. We had a lot of questions - what does this diagnosis mean? Will this affect me for the rest of my life? Is there a specialist we should speak to? Is this really happening to me?

A few months later I was diagnosed with an auto-immune disorder known as Antiphospholipid Antibody Syndrome (APS). APS was described by the doctors as a syndrome in which the body recognizes phospholipids (part of a cell's membrane) as foreign and produces antibodies against them thus causing blood clots.

I didn't realize how lucky I was to have been treated so efficiently until almost a year later when I sat in a room at the NATT seminar in Denver. NATT president Mark Jablonski asked how many people had suffered a blood clot. About 60% of the room raised their hands. Mark's next question was - how many of you presented your symptoms to your doctor or some other medical professional and were correctly diagnosed? Out of the 60% only about five of us raised our hands.

Now at age 31, almost two years after this life-altering event, my husband and I face the challenges of living with this disorder. We hope to help spread awareness about the many different types of blood clotting disorders by telling our story. Maybe we can be a comfort to others who have had similar experiences. Maybe we can help prevent them from happening at all.

UPDATES FROM THE EDUCATION COMMITTEE

The year 2004 has been a great one for the NATT Education Committee! Perhaps our biggest accomplishment has been the November launching of the NATT Website at www.nattinfo.org. Our committee worked hard to assemble up-to-date literature that we hope will be of interest to all individuals who are affected by thrombosis and thrombophilia.

While we are happy to have the website up and running, we still know there is a lot of room for growth and improvement. Our committee is hard at work to develop NATT brochures on relevant topics, and we hope to have available in print and on the web. Committee member **Tom Hogan** has developed a glossary of thrombosis/thrombophilia terms, which is now available on the web. Members **Cindy Kos** and **Laura-Jean Siggins** have been tackling an informational brochure on the psychosocial impact of thrombosis, particularly for teens. Medical Advisor **Ed Libby** has been developing a NATT education brochure on treatment and medications for thrombosis patients. I have been working on a brochure called "Family Testing for the Thrombophilias," to address issues of genetic testing and talking to relatives.

At the NATT Education Conferences you told us that these issues were important to you—that is why we are addressing these topics first. However, there are many more on our list for 2005—including specific fact sheets for each thrombophilia, tackling insurance issues, pregnancy and thrombophilia, and specific information for kids.

We presented a compilation of your feedback from our education seminars at a meeting hosted for Thrombosis health care professionals at the Centers for Disease Control in Atlanta in January. The response was amazing, with several health care providers expressing an interest in NATT, and hoping to contribute their medical knowledge through NATT Education projects. We are looking forward to continued partnerships, so that education materials can be developed for you.

Also in 2005, we hope to vamp up our "News and Events" section to keep you informed of the latest information and research regarding thrombosis and thrombophilia. We are working with the Medical and Scientific Advisory Board to compile important medical recommendation papers pertaining to thrombosis and thrombophilia to help educate health care providers. We hope to provide access to these documents through our website. Keep your eye out for this update in the coming months.

Best wishes for a happy and healthy 2005!

Elizabeth Varga, M.S.
CHAIR-NATT EDUCATION COMMITTEE
MASAB



In Loving Memory of **JESSICA RUTH EARLEY**

Daughter of NATT member Kathy H. Earley - Belmont, NC

Jessica Earley was on the Dean's List, a junior Communications Major at Appalachian State University, Boone, NC. Jessica had just celebrated her 21st birthday on Sunday, April 27, 2003, one week after Easter. She insisted on completing her exams after being diagnosed with an enlarged liver. She was hospitalized in Charlotte, the day after exams where she was diagnosed with FVL and a severe blood clot. She was Aerovaced by helicopter to UNC Hospital - Chapel Hill on May 9, 2003.

Jessica passed away on Friday, May 23, 2003. Her entire story will be in the next issue of the NATT newsletter!

Did we hit our target? How can we improve our newsletter?

We would like to know what you think.
Please forward any comments and
suggestions to NATT'S Communication
Committee at

NATTINFO@YAHOO.com

Your input is very much appreciated!

NO FDA APPROVAL FOR NEW ORAL BLOOD THINNER EXANTA[®]

Dr. Stephan Moll, MASAB Chair

New drug development (or reformulation of current ones) usually results from consumer and medical provider interest in providing medications that are easier to take, require less monitoring, have fewer side effects, and may work in new or different ways. By making these improvements, increased adherence to medical treatment may result – a "win-win" for physicians and patients alike. NATT desires to keep its readers informed of such developments. The following article highlights one new drug that may prove promising in the treatment of blood clots or the prevention of them after certain surgical procedures. As other new drugs become available or studied, we will provide similar reviews.

Exanta[®] is the brand name for the oral blood thinner, Ximelagatran, developed by Astra-Zeneca. A small synthetic molecule, Exanta[®] inhibits clotting by blocking one of the major clotting proteins, thrombin. Scientists refer to it as an "oral thrombin inhibitor." Several studies have been published in major medical journals about its use in large clinical comparison trials. Results of these studies mostly have shown that Exanta[®] is at least as effective as other forms of anticoagulation medications (such as low molecular weight heparin and warfarin) in prevention or treatment of blood clots and strokes. One key study showed that Exanta[®] taken long-term is very effective and, from a bleeding point of view, very safe in preventing deep vein thrombosis (=DVT) recurrences in patients who have had DVT in the past.

Some very promising features of this drug:

- can be given orally (twice a day),
- does not need any monitoring, i.e. has a very predictable blood-thinning effect - "one dose fits all",
- is immediately active, thus initial heparin therapy in acute DVT/PE may not be necessary,
- has no interaction with vitamin K in the diet, thus patients can eat what they want,
- has a short half-life (thus, can be

discontinued at times of surgery 12-24 hours before surgery).

In May 2004, Exanta[®] was approved by European regulatory agencies (equivalent to the U.S. FDA) for use in DVT prophylaxis after hip and knee replacement. It is commercially available in some European countries. However, on Sept 10th, 2004, a medical advisory panel recommended to the US FDA not to approve the drug for the 3 indications that the drug's company was seeking:

1. Long-term prevention of DVT in patients who have already had one leg clot,
2. Stroke prevention in patients with irregular heart beat (atrial fibrillation),
3. Prevention of leg clots (deep vein thrombosis = DVT) after major orthopedic surgery (hip and knee replacement).

The reasons for the recommendation not to approve the drug were concerns about its safety, and, to a lesser degree, its efficacy. There were more incidents of severe liver toxicity and heart attacks in patients using

Exanta[®] versus those treated with warfarin. Criticism also arose regarding frequency of lab monitoring for liver toxicity suggested by the company. The advisory panel felt once a month testing was too infrequent to detect patients that may develop liver problems. Lastly, in one study Exanta[®] was actually less effective as a prevention of DVT than other methods. Exanta[®]-treated patients also had a slightly higher rate of heart attacks. For more specific information about these studies, contact your hematologist.

Therefore, on October 11th, 2004, Astra-Zeneca was informed in a letter by the FDA that it did not approve Exanta[®]. It is not clear what Astra-Zeneca will do now – whether it will terminate development of the drug or whether it will do further research and additional clinical trials. The good news for patients and health care providers is: several other oral blood thinners produced by various pharmaceutical companies are in development and are entering clinical trials, even though they are all still early in their development. Maybe in 3 or 4 years an oral blood thinner will be available as an alternative to warfarin, that is effective, safe, and does not require monitoring.

Join Us!

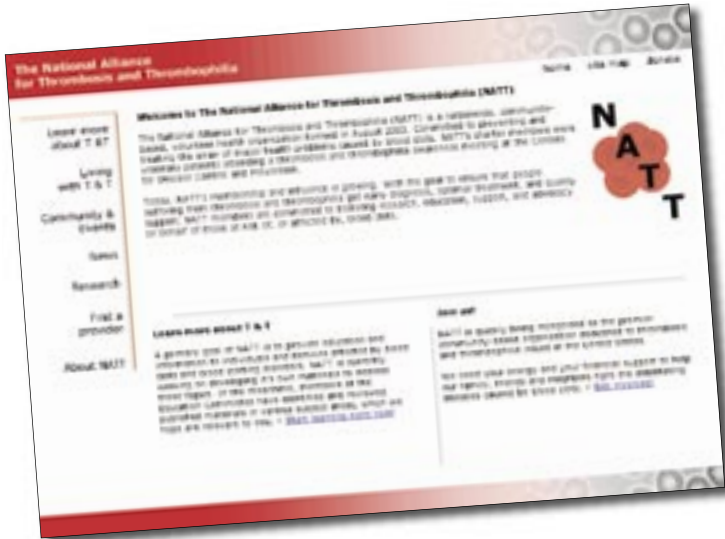
NATT is quickly being recognized as the premier community-based organization dedicated to prevention and treatment issues in thrombosis and thrombophilia in the United States.

Join Us! We need your energy and your financial support to help our family, friends, and neighbors fight the debilitating conditions caused by blood clots. The specific skill sets we are looking for include:

- **Fundraising experience**
- **Communication experience**
- **Web hosting/web master experience**
- **Finance experience**
- **Advocacy experience**
- **Volunteer coordinator experience**
- **Patient/family support group experience**

Thank you in advance for your support and your time. Please contact:

Mr. Tom Hogan
NATT Secretary
(860) 376-3250
nattinfo@yahoo.com



View our website:

www.nattinfo.org

NATT Donations

The National Alliance for Thrombosis and Thrombophilia is chartered as a charitable 501c3. Your contributions are needed to drive our progress.

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Thank you for your support!

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